

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

SRL 6109

09/249,220

## LIST OF PRIOR ART CITED BY APPLICANT

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APPLICANT

Richard A. Mueller et al.

FILING DATE

2/12/99

GROUP

1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
F.GH	1	3,590,028	6/1971	Arcamone	260	210	
"	2	4,012,448	3/1977	Smith et al.	260	591	
"	3	4,065,562	12/1977	Ohata et al.	424	267	
"	4	4,182,767	1/1980	Murai et al.	424	267	
"	5	4,260,622	4/1981	Junge et al.	424	267	
"	6	4,327,725	5/1982	Cortese et al.	128	260	
"	7	4,524,060	6/1985	Mughal et al.	424	19	
"	8	4,533,668	8/1985	Matsumura et al.	514	321	
"	9	4,611,058	9/1986	Koebornick	546	242	
"	10	4,612,008	9/1986	Wong et al.	604	892	
"	11	4,639,436	1/1987	Junge et al.	514	24	
"	12	4,765,989	8/1988	Wong et al.	424	473	
"	13	4,783,337	11/1988	Wong et al.	424	468	
"	14	4,806,650	2/1989	Schröder et al.	546	242	
"	15	4,849,430	7/1989	Fleet et al.	514	315	
"	16	4,880,830	11/1989	Rhodes	424	470	
"	17	4,957,926	9/1990	Jacob et al.	514	315	
"	18	5,003,072	3/1991	Partis et al.	546	243	
"	19	5,011,829	4/1991	Hirsch et al.	514	50	
"	20	5,030,638	7/1991	Partis et al.	514	315	
"	21	5,041,441	8/1991	Radin et al.	514	237.8	
"	22	5,068,112	11/1991	Samejima et al.	424	495	
"	23	5,190,765	3/1993	Jao et al.	424	473	

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F.G.H	24	5,144,037	9/1992	Partis et al.	546	116	
"	25	5,151,519	9/1992	Behling et al.	546	219	
"	26	5,281,724	1/1994	Behling et al.	549	334	
"	27	5,310,745	5/1994	Partis et al.	514	315	
"	28	5,331,096	7/1994	Koszyk et al.	546	115	
"	29	5,411,970	5/1995	Partis et al.	514	315	
"	30	5,451,679	9/1995	Barta et al.	546	219	
"	31	5,472,969	12/1995	Platt et al.	514	315	
"	32	5,491,135	2/1996	Blough	514	115	
"	33	5,525,616	6/1996	Platt et al.	514	315	
"	34	5,536,732	7/1996	Lesur et al.	514	317	
"	35	5,595,981	1/1997	Barta et al.	514	63	
"	36	5,612,480	3/1997	Barta et al.	544	180	
"	37	5,663,342	9/1997	Barta et al.	546	6	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
F.B.H	38	2,020,278	3/1979	U.K.	<del>G07D</del>	211/40		
"	39	0 324 328	7/1989	EPO	<del>A61K</del>	31/445		
"	40	0 350 012	1/1990	EPO	A61K	31/445		
"	41	0 367 748	5/1990	EPO	C07D	211/46		
"	42	0 449 026	10/1991	EPO	C07D	491/04		
"	43	0 494 850	7/1992	EPO	C07D	211/46		
"	44	0 566 556	10/1993	EPO	C07D	211/40		
"	45	WO87/03903	7/1987	PCT	C12N	05/00		
"	46	WO93/18763	9/1993	PCT	A61K	31/195		

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F.G.H	47	WO95/06061	3/1995	PCT	C07K	5/03		
"	48	WO95/19172	7/1995	PCT	A61K	31/445		
"	49	WO95/22975	8/1995	PCT	A61K	31/445		
"	50	WO96/40110	12/1996	PCT	A61K	31/35		
"	51	WO97/00881	1/1997	PCT	C07H	17/02		No
"	52	WO98/35685	8/1998	PCT	A61K	31/70		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

F.G.H	53	Dalton, et al., "A Phase II Randomized Study of Oral Verapamil as a Chemosensitizer to Reverse Drug Resistance in Patients with Refractory Myeloma," February 1, 1995, Cancer, Vol. 75, No. 3, pp. 815-820						
"	54	Jacob et al., "Aminosugar Attenuation of HIV Infection," 1992, Natural Products as Antiviral Agents, pp. 137-152						
"	55	Karpas, et al., "Aminosugar Derivatives as Potential Anti-Human Immunodeficiency Virus Agents," December, 1988, Proc. Natl. Acad. Sci., Vol. 85, pp. 9229-9233						
"	56	Welsh, et al., "Accumulation of Fatty Alcohol in MCF-7 Breast Cancer Cells," November 15, 1994, Archives of Biochemistry and Biophysics, Vol. 315, No. 1, pp. 41-47						
"	57	Blum et al., "Antiviral Therapy of Hepatitis B Virus Infection: Blocking Viral Gene Expression," June 1995, Elsevier Science, B.V., Advanced Drug Delivery Reviews 17, pp. 321-331						
"	58	Lu, et al., "Aberrant Trafficking of Hepatitis B Virus Glycoproteins in Cells in Which N-glycan Processing is Inhibited," March 1997, Proc. Natl. Acad. Sci., Vol. 94, pp. 2380-2385						
"	59	Korba, et al., "Antiviral Effectiveness of 3TC, Fanciclovir, and Interferon Against Chronic WHV Replication-Potential for Combination Therapy," September 1996, Molecular Biology of Hepatitis B Viruses Meeting, p. 201						
"	60	Lavie, et al., "Agents that Reverse Multidrug Resistance, Tamoxifen, Verapamil, and Cyclosporin A, Block Glycosphingolipid Metabolism by Inhibiting Ceramide Glycosylation in Human Cancer Cells," August 20, 1996, The Journal of Biological Chemistry, Vol. 272, No. 3, pp. 1682-1687						
"	61	Lavie et al., "Accumulation of Glucosylceramides in Multidrug-Resistant Cancer Cells," August 9, 1996, The Journal of Biological Chemistry, Vol. 271, No. 32, pp. 19530-19536						
"	62	Inokuchi, et al., "Antitumor Activity Via Inhibition of Glycosphingolipid Biosynthesis," September 3, 1987, Cancer Letters, Vol. 38, pp. 23-30						
"	63	Dienstag, et al., "A Preliminary Trial of Lamivudine for Chronic Hepatitis B Infection," December 21, 1995, The New England Journal of Medicine, Vol. 333, No. 25, pp. 1657-1661						
"	64	Holleran, et al., "Characterization of Cellular Lipids in Doxorubicin-Sensitive and -Resistant P388 Mouse Leukemia Cells," 1986, Cancer Chemother Pharmacol, 17:11-15						

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LIST OF PRIOR ART CITED BY APPLICANT  (Use several sheets if necessary)				APPLICANT Richard A. Mueller et al.	
				FILING DATE 2/12/99	
				GROUP 1614	
F.G.H		65	Fisher, et al., "Clinical Studies with Modulators of Multidrug Resistance," April 1995, Drug Resistance in Clinical Oncology and Hematology, Vol. 9, No. 2, pp. 363-382		
"		66	Raderer, et al., "Clinical Trials of Agents that Reverse Multidrug Resistance," December 15, 1993, Cancer, Vol. 72, No. 12, pp. 3553-3563		
"		67	Tan, et al., "Chemical Modification of the Glucosidase Inhibitor 1-Deoxynojirimycin," August 5, 1991, The Journal of Biological Chemistry, Vol. 266, No. 22, pp. 14504-14510		
"		68	Wang, et al., "Chemo-enzymatic Synthesis of Five-membered Azasugars as Inhibitors of Fucosidase and Fucosyltransferase: An Issue Regarding The Stereochemistry Discrimination at Transition States," 1993, Tetrahedron Letters, Vol. 34, No. 3, pp. 403-406		
"		69	Jezowska-Bojczuk, et al., "Copper(II) Interactions with an Experimental Antiviral Agent, 1-Deoxynojirimycin, and Oxygen Activation by Resulting Complexes," 1996, Journal of Inorganic Biochemistry, Vol. 64, pp. 231-246		
"		70	Ramu, et al., "Differences in Lipid Composition of Doxorubicin-Sensitive and -Resistant P388 Cells," April 1984, Cancer Treatment Reports, Vol. 68, No. 4, pp. 637-641		
"		71	Beketic-Oreskovic, et al., "Decreased Mutation Rate for Cellular Resistance to Doxorubicin and Suppression of mdr1 Gene Activation by the Cyclosporin PSC 833," November 1, 1995, Journal of the National Cancer Institute, Vol. 87, No. 21, pp. 1593-1602		
"		72	Coates, et al., "Developments in Viral Hepatitis During 1994," 1995, Exp. Opin. Ther. Patents, 5(8): 747-756		
"		73	Korba, et al., "Effectiveness of Combination Therapies with 3TC, Fanciclovir, and Alpha Interferon Against Woodchuck Hepatitis Virus Replication in Chronically-Infected Woodchucks: Model for Potential Anti-HBV Treatments," April 1997, Antiviral Research, Vol. 34, No. 2, p. A52		
"		74	Volm, et al., "Expression of Resistance Factors (P-Glycoprotein, Glutathione S-Transferase-II, and Topoisomerase II) and Their Interrelationship to Proto-Oncogene Products in Renal Cell Carcinomas," June 15, 1993, Cancer, Vol. 71, No. 12, pp. 3981-3987		
"		75	Lu, et al., "Evidence That N-Linked Glycosylation is Necessary for Hepatitis B Virus Secretion," November 10, 1995, Virology, Vol. 213, No. 2, pp. 660-665		
"		76	Wiltink, "Future Prospects in Antiviral Therapy," June 1992, Pharmaceutisch Weekblad Scientific Edition, 14(4A), pp. 268-274		
"		77	Bohuis, et al., "Mechanisms of Multidrug Transporters," 1997, FEMS Microbiology Reviews 21, pp. 55-84		
"		78	Legler, et al., "Glycosylceramidase from Calf Spleen: Characterization of its Active Site with 4-n-Alkylumbelliferyl $\beta$ -glucoside and N-alkyl Derivatives of 1-Deoxynojirimycin," December 1985, Bio-ChemHoppe-Seyler, Vol. 366, pp. 1113-1122		
"		79	Hardman, et al., "Goodman & Gilman's The Pharmacological Basis of Therapeutics," 1996, McGraw-Hill, Ninth Edition, Chapter 32: Drugs Used for the Treatment of Myocardial Ischemia," Verapamil, pp. 767-774, 780-781, 799-801, and 829		

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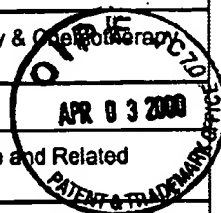
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E.G.H	80	Mehta, et al., Hepatitis B Virus (HBV) Envelope Glycoproteins Vary Drastically in Their Sensitivity to Glycan Processing: Evidence that Alteration of a Single N-Linked Glycosylation Site Can Regulate HBV Secretion," March 1997, Proc. Natl. Acad. Sci., Vol. 94, pp. 1822-1827
~	81	Locamini, et al., "Hepatitis B: New Approaches for Antiviral Chemotherapy," 1996 Antiviral Chemistry & Chemotherapy 7(2), pp. 53-64
~	82	Hollinger, "Hepatitis B Virus," Field Virology, Third Edition, Chapter 86, pp. 2739-2807
~	83	Doong, et al., "Inhibition of the Replication of Hepatitis B Virus <i>In Vitro</i> by 2',3'-dideoxy-3'-thiacytidine and Related Analogues," October 1991, Proc. Natl. Acad. Sci., Vol. 88, pp. 8495-8499
"	84	Fleet, et al., "Inhibition of HIV Replication by Amino-Sugar Derivatives," September 1988, Federation of European Biochemical Societies, Vol. 237, No. 1,2, pp. 128-132
"	85	Newburn, et al., "Inhibition by Acarbose, Nojirimycin and 1-Deoxynojirimycin of Glucosyltransferase Produced by Oral <i>Streptococci</i> ," 1983, Archs Oral Biol., Vol. 28, No. 6, pp. 531-536
"	86	Saunier, et al., "Inhibition of N-Linked Complex Oligosaccharide Formation by 1-Deoxynojirimycin, An Inhibitor of Processing Glucosidases," December 10, 1982, The Journal of Biological Chemistry, Vol. 257, No. 23, pp. 14155-14161
"	87	Abe, et al., "Induction of Glycosylceramide Synthase by Synthase Inhibitors and Ceramide," 1996, Biochimica et Biophysica Acta, Vol. 1299, pp. 333-341
"	88	Abe, et al., "Improved Inhibitors of Glucosylceramide Synthase," 1992, J. Biochem., Vol. 111, pp. 191-196
"	89	Tan, et al., "Introduction of Oxygen into the Alkyl Chain of N-decyl-dNM Decreases Lipophilicity and Results in Increased Retention of Glucose Residues on N-Linked Oligosaccharides," 1994, Glycobiology, Vol. 4, No. 2, pp. 141-149
"	90	Elbein, "Inhibitors of the Biosynthesis and Processing of N-Linked Oligosaccharide Chains," 1987, Ann. Rev. Biochem., 56:497-534
"	91	Radin, et al., "Inhibitors of Cerebroside Metabolism," 1981, Methods in Enzymology, Vol. 72, pp. 673-684
"	92	Prence, et al., "In Vitro Accumulation of Glucocerebroside in Neuroblastoma Cells: A Model for Study of Gaucher Disease Pathobiology," 1996, Journal of Neuroscience Research, 43:365-371
"	93	Korba, "In Vitro Evaluation of Combination Therapies Against Hepatitis B Virus Replication," 1995, Antiviral Research, Vol. 29, pp. 49-51
"	94	Bradley, et al., "Mechanism of Multidrug Resistance," 1988, Biochimica et Biophysica Acta, Vol. 948, pp. 87-128
"	95	Mülder, et al., "Multidrug Resistance-Modifying Components in Human Plasma with Potential Clinical Significance," January 1996, Journal of Experimental Therapeutics & Oncology, Vol. 1, No. 1, pp. 13-22
"	96	Ardalan, et al., "Mechanism of Action of a New Antitumor Agent, Carbeltimer," November 1986, Cancer Research, Vol. 46, pp. 5473-5476



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F.G.H	97	Platt, et al., "Modulation of Cell-Surface Transferrin Receptor by the Imino Sugar N-butyldeoxynojirimycin," 1992, Eur. J. Biochem., Vol. 208, pp 187-193
~	98	Kawakami, et al., "Monoclonal Antibodies with Affinity to Self-Complementary Left-Handed DNA Containing Cyclonucleosides with High Anti Conformation," 1994, Nucleosides & Nucleotides, Vol. 13(1-3), pp. 421-427
~	99	Dicato, et al., "Multidrug Resistance: Molecular and Clinical Aspects," 1997, Cytokines, Cellular & Molecular Therapy, Vol. 3, No. 2, pp. 91-100
~	100	Bolhuis, et al., "Mechanisms of Multidrug Transporters," 1997, FEMS Microbiology Reviews, Vol. 21, pp. 55-84
~	101	Carbohydrate Chemistry, "Chapter 20: Nucleosides," undated, pp. 242-276
~	102	Platt, et al., "N-Butyldeoxynojirimycin Is a Novel Inhibitor of Glycolipid Biosynthesis: Secretion of Human Hepatitis B Virus Is Inhibited by the Imino Sugar N-Butyldeoxynojirimycin," 1994, Chemtracts—Organic Chemistry, Vol. 7, pp. 106-107
~	103	Platt, et al., "N-Butyldeoxynojirimycin Is a Novel Inhibitor of Glycolipid Biosynthesis," March 18, 1994, The Journal of Biological Chemistry, Vol. 269, No. 11, pp. 8362-8365
~	104	Platt, et al., "N-Butyldeoxygalactonojirimycin Inhibits Glycolipid Biosynthesis but Does Not Affect N-Linked Oligosaccharide Processing," October 28, 1994, The Journal of Biological Chemistry, Vol. 269, No. 43, pp. 27108-27114
~	105	Platt, et al., "New Approach for the Treatment of Gauchers Disease," March 1996, Gauchers Association Newsletter, one page
~	106	Wilson, et al., "Nitrogen Glycosylation Reactions Involving Pyrimidine and Purine Nucleoside Bases with Furanoside Sugars," December 1995, Synthesis, Department of Chemistry, Emory University, pp. 1465-1479
~	107	Kers, et al., "Nucleoside Phosphonates. Development of Synthetic Methods and Reagents," 1996, Nucleosides & Nucleotides, 15(1-3), pp. 361-378
~	108	Tsuruo, et al., "Overcoming of Vincristine Resistance in P388 Leukemias <i>In Vivo</i> and <i>In Vitro</i> Enhanced Cytotoxicity of Vincristine and Vinblastine by Verapamil," May 1981, Cancer Research, Vol. 41, pp. 1967-1972
~	109	Wright, et al., "Phospholipid and Ether Linked Phospholipid Content Alter with Cellular Resistance to Vinblastine," December 17, 1985, Biochemical and Biophysical Research Communications, Vol. 133, No. 2, pp. 539-545
~	110	Bradley, et al., "P-glycoprotein, Multidrug Resistance and Tumor Progression," 1994, Cancer and Metastasis Reviews, Vol. 13, pp. 223-233
~	111	May, et al., "Plasma Membrane Lipid Composition of Vinblastine Sensitive and Resistant Human Leukaemic Lymphoblasts," 1988, Int. J. Cancer, Vol. 42, pp. 728-733
~	112	Mutchnick, et al., "Prospectives on the Treatment of Chronic Hepatitis B and Chronic Hepatitis C with Thymic Peptides and Antiviral Agents," 1994, Antiviral Research, Vol. 24, pp. 245-257

EXAMINER <i>Enida Chashyha</i>	DATE CONSIDERED <i>NOV, 17, 2000</i>
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FIGH	113	Platt, et al., "Prevention of Lysosomal Storage in Tay-Sachs Mice Treated with N-Butyldoxynojirimycin," April 18, 1997, Science, Vol. 276, pp. 428-431
"	114	Wishart, et al., "Quinidine as a Resistance Modulator of Epirubicin in Advanced Breast Cancer: Mature Results of a Placebo-Controlled Randomized Trial," September 1994, Journal of Clinical Oncology, Vol. 12, No. 9, pp. 1771-1777
"	115	Chabner, et al., "Reversal of Multidrug Resistance," January 1991, Journal of Clinical Oncology, Vol. 9, No. 1, pp. 4-6
"	116	Hui, et al., "Reduced p21 <sup>WAF1/CIP1</sup> Expression and p53 Mutation in Hepatocellular Carcinomas," March 1997, Hepatology, Vol. 25, No. 3, pp. 575-579
"	117	Radin, "Rationales for Cancer Chemotherapy with PDMP, a Specific Inhibitor of Glucosylceramide Synthase," 1994, Molecular and Chemical Neuropathology, Vol. 21, pp. 111-127
"	118	Arends, "Recueil des Travaux Chimiques des Pays-Bas," Journal of the Royal Netherlands Chemical Society, February 1994, Recl. Trav. Chim. Pays-Bas 113, 63-114, contents page only
"	119	Shukla, et al., "Rapid Kidney Changes Resulting from Glycosphingolipid Depletion by Treatment with a Glucosyltransferase Inhibitor," 1991, Biochimica et Biophysica Acta., Vol. 1083, pp. 101-108
"	120	Rosina, et al., "Recent Developments in the Treatment of Hepatitis D Infection," 1996, Anti-infectives - Section Review, Exp. Opin. Invest. Drugs, No. 5(2), pp. 197-205
"	121	Gish, et al., "Recent Developments in the Treatment of Chronic Hepatitis B Virus Infection," 1995, Exp. Opin. Invest. Drugs, 4(2), pp. 95-115
"	122	Block, et al., "Secretion of Human Hepatitis B Virus is Inhibited by the Imino Sugar N-butyldoxynojirimycin," March 1994, Proc. Natl. Acad. Sci., Vol. 91, pp. 2235-2239
"	123	Inokuchi, et al., "Stimulation of Glycosphingolipid Biosynthesis by L-Threo-1-Phenyl-2-Decanoylamino-1-Propanal and Its Homologs in B16 Melanoma Cells," 1995, J. Biochem., Vol. 117, No. 4, pp. 766-773
"	124	Abe, et al., "Structural and Stereochemical Studies of Potent Inhibitors of Glucosylceramide Synthase and Tumor Cell Growth," 1995, Journal of Lipid Research, Vol. 36, pp. 611-621
"	125	Ogawa, et al., "Synthesis of Potent $\beta$ -D-Glucocerebrosidase Inhibitors: N-Alkyl- $\beta$ -Valienamines," 1996, Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 8, pp. 929-932
"	126	Vorbrüggen, et al., "Some Recent Trends and Progress in Nucleoside Synthesis," 1996, Acta Biochimica Polonica, Vol. 43, No. 1, pp. 25-36
"	127	Sobrero, et al., "Sequential Dichloromethotrexate (DCM) and 5-Fluorouracil (FU): A Synergistic Combination Potentially Valuable for Hepatic Artery Infusion Therapy," March 1983, ASCO Abstracts, Clinical Pharmacology, Vol. 2, Article C-102, p. 26
"	128	Wadkins, et al., "The Role of Drug-Lipid Interactions in the Biological Activity of Modulators of Multi-Drug Resistance," 1993, Biochimica et Biophysica Acta, Vol. 1153, pp. 225-236

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F-61+	129	Doige, et al., "The Effects of Lipids and Detergents on ATPase-Active P-Glycoprotein," 1993, Biochimica et Biophysica Acta, Vol. 1146, pp. 65-72			
"	130	Ries, et al., "Treatment of Advanced and Refractory Breast Cancer with Doxorubicin, Vincristine and Continuous Infusion of Verapamil. A Phase I-II Clinical Trial," 1991, Med. Oncol. & Tumor Pharmacother, Vol. 8, No. 1, pp. 39-43			
"	131	Dushenko, "Treatment and Prevention of Chronic Viral Hepatitis," 1995, Pharmac. Ther., Vol. 65, pp. 47-73			
"	132	Block, et al., "Treatment of Chronic Hepadnavirus Infection in a Woodchuck Animal Model with an Inhibitor of Protein Folding and Trafficking," May 1998, Nature Medicine, Vol. 4, No. 5, pp. 610-614			
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EXAMINER <i>Fayiba Chahghave</i>	DATE CONSIDERED <i>NOV. 17, 2000</i>
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT(S) (Use several sheets if necessary)				APPLICANT Richard A. Mueller et al. <b>AUG 16 2000</b>	
				FILING DATE February 12, 1999	GROUP 1814
<i>FGH</i>	144	van den Broek, et al., "Synthesis of Oxygen-Substituted N-alkyl 1-deoxynojirimycin derivatives: aza sugar $\alpha$ -glucosidase inhibitors showing antiviral (HIV-1) and immunosuppressive activity," <i>Recl. Trav. Chim. Pays-Bas</i> 113, 1994, pp. 507-516			
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EXAMINER <i>Farika Ghoshghaee</i>	DATE CONSIDERED <i>Nov 17, 2000</i>
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